

REAL WORLD TESTING PLAN

GENERAL INFORMATION

Plan Report ID Number	20241107wlg
Developer Name	Welligent, Part of the ContinuumCloud
Product Name(s)	Welligent
Version Number(s)	8MU3
Certified Health IT Product List (CHPL) ID(s)	15.02.05.2536.WELL.01.01.1.220201
Developer Real World Testing Plan Page URL	https://www.welligent.com/solutions/meaningful-health/

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Real World Testing will be performed in concert with authorized representatives and providers in order to ensure Welligent’s contribution towards Quality of Care, as well as conformance with ONC’s Certification Criteria for the following measures:

- § 170.315(b)(1) Transitions of care
- § 170.315(b)(2) Clinical information reconciliation and incorporation
- § 170.315(b)(10) Electronic Health Information export
- § 170.315(g)(7) Application access - patient selection
- § 170.315(g)(9) Application access - all data request
- § 170.315(g)(10) Standardized API for patient and population services - all data request
- § 170.315(h)(1) Direct Project.

The Welligent platform is designed for interoperability. Given the focus of the ONC Certification criteria on interoperability through secure and standardized transmission of patient health information, whether between providers using different EHRs or upon request by patients themselves, we elected to structure our Real World Testing procedures closely to the ONC testing procedure in order to best showcase these capabilities in the Welligent platform.

Welligent’s method for accurate and consistent testing will involve coordination with our partners as well as regular collection and analysis of data in order to identify any issues with the collection or data itself. This will involve regular follow-up with our providers and authorized representatives in addition to our scheduled quarterly collation and analysis.

A successful Real World Testing round will be measured by accurate data collection, consistency adhering to our timelines as described below, and adjustments to process or technology as analysis illuminates any gaps or data issues.

STANDARDS UPDATES

No voluntary SVAP standards updates.

CARE SETTING

Users of the Welligent software are performing services and providing care in the ambulatory care setting as opposed to in an inpatient environment. Thus, we have chosen to perform our real-world testing in the ambulatory care setting.

METRICS USED IN OVERALL APPROACH

CARE COORDINATION & ELECTRONIC EXCHANGE

Description of Metric

The following outlines the metrics that have been identified to best demonstrate conformance to certification criteria § 170.315(b)(1) Transition of Care and § 170.315(h)(1) Direct Project, across two use cases (single patient and population services).

To demonstrate sending and receiving Transition of Care (TOC) messages with other providers to close the referral loop, the patient's ePHI will be exchanged using a C-CDA 2.1 Care Referral or Referral Note and DIRECT secure messaging for data transport.

Metric	Description	Justification
Outbound TOC's received by HISP	100 percent of outbound TOC's successfully received by HISP	<ol style="list-style-type: none">1. Showcase ConnectEHR's streamlined approach to provider-to-provider patient referrals and transitions of care with the goal being higher quality patient care.2. Reduce risk of manual data entry referral errors by transmitting patient data securely and electronically.3. Improved efficiency by reducing necessary manual data entry.4. Ensure private and secure transmission of patients' PHI.5. Increased interoperability between disparate HIT systems.
C-CDA scorecard	Average C-CDA grade from scorecard for C-CDAs generated from ConnectEHR is a "C" or better	
C-CDA's flagged as restricted received flagged as restricted per the trading partner	75 percent of C-CDAs flagged as restricted were received in restricted status based on confirmed receipt from trading partner	
Trading Partner's TOC C-CDAs received by ConnectEHR	75 percent of trading partner's TOC C-CDAs successfully received by ConnectEHR.	

Associated Certification Criteria

Associated Certification Criteria	Relied Upon Software (if applicable)
§ 170.315(b)(1) Transition of Care	ConnectEHR
§ 170.315(h)(1) Direct Project	MaxMD

Test Procedure

Step	Testing Procedure:	Expected Outcomes:	Key Milestone Dates
1	Identify Trading Partner (TP) and coordinate with TP for sending/receiving clinical documents using production data as described in this RWT plan.	<ul style="list-style-type: none"> • Confirm Trading Partner • Confirm ability to send and receive clinical documents • Confirm with TP that production data will be used, whether in an actual live environment or a copy of a live environment 	Begin test: Q4, 2025
2		<ul style="list-style-type: none"> • USCDIv1 data elements captured in EHR • Care provider selects Clinical Document to be transmitted. • Care provider is able to create a C- CDA Release 2.1 that also includes the reason for referral, and the referring or transitioning provider's name and office contact information. • Care provider flags the document as restricted and subject to restrictions on re-disclosure. 	
3	Care provider initiates TOC to TP EHR in EHR	<ul style="list-style-type: none"> • Care provider selects recipient from directory of Direct addresses and initiates sending of Clinical Document. The user is able to create a C-CDA Release 2.1 that also includes the reason for referral, and the referring or transitioning provider's name and office contact information. • C-CDA Care Referral or Referral Note is triggered to send via Direct Protocol • Care provider reviews the Direct Status screen (under Direct Outgoing menu choice) to ensure Clinical Document was successfully transmitted. 	
4	Validate that C-CDA for Patient A contains USCDIv1 data elements.	Recipient uses scorecard to grade C- CDA	
5	Trading partner refers Patient B from TP EHR to system under test by generating C- CDA Clinical Document or Referral Note.	<ul style="list-style-type: none"> • Care provider flags Social History section of C-CDA as restricted. • Care provider selects recipient from directory of Direct addresses and initiates sending of Clinical Document. 	
6	In system under test, tester acknowledges receipt of valid Clinical Document.	<ul style="list-style-type: none"> • Tester uses Document Center to locate Clinical Document. • Care provider reviews the Direct Status screen (under Direct Outgoing menu choice). • Recipient validates that Social History section of C-CDA is flagged as restricted 	
7	Calculate and compile metrics		Complete test: Q4 2025

Description of Metric

The following outlines the metrics that have been identified to best demonstrate conformance to certification criteria § 170.315(b)(2) Clinical information reconciliation and incorporation across two use cases (single patient and population services).

Metric	Description	Justification
Data Completeness	<p>100% of incoming patient data is successfully reconciled into the EHR with focus on the below data elements:</p> <ul style="list-style-type: none"> • Demographics • Problems • Medication • Allergies 	Facilitate interoperability by ensuring patient data transferred between disparate HIT is accurately received and incorporated.

Associated Certification Criteria

Associated Certification Criteria	Relied Upon Software (if applicable)
§ 170.315(b)(2) Clinical information reconciliation and incorporation	ConnectEHR

Test Procedure

Step	Testing Procedure:	Expected Outcomes:	Key Milestone Dates
1	Using production data in an actual live environment or copy of live environment, demonstrate the ability to import medication, allergy, and problem data for a specified client.	<ul style="list-style-type: none"> • Specified client can be selected through the UL. • Medication, allergy, and problem data is sent through UL. 	Begin test: Q4, 2025
2	Demonstrate the ability to limit the set of users who can import data.	Logging in as a User with Admin Profile will allow data to be imported.	
3	Confirm user roles that have been denied import access cannot create import summaries	Logging in as a User with a Non-Admin Profile will not allow access to the export functionality	
4	Verify imported client information matches existing patient in Welligent.	Match the client demographic information to an existing client	
5	Reconcile the medication data imported with medications for the existing patient	Visually verify through a single view which medications match those existing in Welligent for the specific patient and those which do not	

6	Reconcile the allergy data imported with allergy data for the existing patient		
7	Reconcile the problem data imported with problem data for the existing patient		
8	Calculate and compile metrics		Complete test: Q4 2025

Description of Metric

The following outlines the metrics that have been identified to best demonstrate conformance to § 170.315(b)(10) – Electronic Health Information Export.

Metric	Description	Justification
Data Completeness	100% of exported single patient data matches a visual inspection of data in the EHR.	Facilitate interoperability by providing single patient data upon request by the patient, and providing bulk patient data upon request by authorized providers. Export USCDIv1 clinical data for a population of patients for use in a different health information technology product or a third-party system. This export can be used for many purposes, including data portability when a physician practice switches to a new EHR platform.
	The count of patients present in the exported patient population data matches the count of patients in the EHR.	

Associated Certification Criteria

Associated Certification Criteria	Relied Upon Software (if applicable)
§ 170.315(b)(10) – Electronic Health Information export	N/A

Test Procedure 1: Single Patient Export

Step	Testing Procedure:	Expected Outcomes:	Key Milestone Dates
1	Using production data in an actual live environment or copy of live environment, demonstrate the ability to export the full set of data for a single patient.	<ul style="list-style-type: none"> The export can be triggered from within the patient's chart The export can be triggered from a dedicated Print Chart module by searching for a patient using known demographic information 	Start test plan execution: October, 2025
2	Demonstrate the ability to limit the set of users who can access Print Chart functions	Permissions are granted to individual users	
3	Confirm users that have been denied access cannot access Print Chart functions	Users not explicitly granted permission will not be able to access the Print Chart functionality from within a patient's chart or from the dedicated module	

4	Create and validate an export to CSV for a single patient	Confirm all chart data is present in the export	
5	Calculate and compile metrics		Complete test execution: November, 2025

Test Procedure 2: Full EHI Export

Step	Testing Procedure:	Expected Outcomes:	Key Milestone Dates
1	Using production data in an actual live environment or copy of live environment, demonstrate the ability to export the full set of data present in the EHR.	A customer who plans to transfer to another EHR must request a full export of all their EHR data present in Welligent.	Start test plan execution: October, 2025
2	The export must be requested via a ticket created by user and assigned to their Account Manager	Files are provided in CSV format to an SFTP server	
3	Calculate and compile metrics		Complete test execution: November, 2025

APPLICATION PROGRAMMING INTERFACES

Description of Metric

The following outlines the metrics that have been identified to best demonstrate conformance to certification criteria § 170.315(g)(7) Application access— patient selection and § 170.315(g)(9) Application access— all data request across two use cases (single patient and population services).

Enable a patient’s access to their electronic health data through a Personal Health Record (PHR) app on their smartphone. They have had a healthcare encounter with a provider using an EHR that is integrated with the Dynamic FHIR API and Patient Portal modules of ConnectEHR. They would like to view the results from that encounter along with the rest of their electronic health record.

Metric	Description	Justification
PHR Access	Patient can retrieve FHIR API data from PHR app for 100 percent of encounters.	Making an electronic copy of the health record available empowers patients to become more involved and knowledgeable of their health care. This allows communication and collaboration with the patient’s medical providers leading to improvement in overall population health.
PHR Data Accuracy	In 100 percent of encounters from Step #1, PHR data matches data from EHR. This will be confirmed by visual validation of the following FHIR resources: Demographics Problems Medications Allergies	

Associated Certification Criteria

Associated Certification Criteria	Relied Upon Software (if applicable)
§ 170.315(g)(7) Application access— patient selection	Dynamic FHIR API
§ 170.315(g)(9) Application access— all data request	Dynamic FHIR API (Version FHIR4-B)

Test Procedure

Step	Testing Procedure:	Expected Outcomes:	Key Milestone Dates
1	Identify Trading Partner (TP) and coordinate with TP for providing patients timely access to their ePHI using production data as described in this RWT plan.	<ul style="list-style-type: none"> Partner with PHR or identify existing PHR that can receive patient clinical data as described in this RWT plan. Ensure that PHR has functionality to access the Dynamic FHIR API, as described here. Partner with EHR that is integrated with the Dynamic FHIR API and Patient Portal modules of ConnectEHR. 	Start test plan execution: October, 2025

2	Patient A has encounter with care provider who uses EHR described above.	Encounter is created and visually confirmed	
3	Provider captures USCDiv1 data elements in EHR	USCDiv1 data elements are validated in the system	
4	Provider manually generates Care/Referral Summary C-CDA post-visit or ensures that the EHR generates one automatically.	C-CDA is confirmed for the specified patient	
5	Patient A uses Dynamic Patient Portal login to view clinical information	<ul style="list-style-type: none"> • Patient Portal automatically sends email reminder that Patient A has a new clinical document available. • Email reminder has a URL/hyperlink to the patient portal. • If patient hasn't already activated their portal account, portal account can be activated via Welcome Email or by an Administrator user 	
6	Patient A uses portal login credentials to log into PHR app	Specific patient ID and token are returned for authentication and data requests Dynamic FHIR API has transformed CCDA into FHIR resources.	
7	PHR app displays full set of data for all data categories	<ul style="list-style-type: none"> • PHR app consumes FHIR resources to populate EHR data 	
8	PHR app returns full set of data for a given category	PHR app will display and all data to be displayed for each data category	
9	PHR app returns data in a computable format using specified standards.	Data is confirmed to be in XML or JSON format	
10	PHR app returns full and accurate data for a specific date and specific date range	<ul style="list-style-type: none"> • Step 10 is optional, if PHR app has the capability to filter by date range • Filtering data by a specific date returns data accurately and as expected • Filtering data by a specific date range returns data accurately and as expected 	
11	Via visual inspection of PHR app, the data is verified to include Assessment, Plan of Treatment and Health concerns are specified as narrative text	Visually validate Assessment, Plan of Treatment and Health Concerns narrative text	
12	Calculate and compile metrics		Complete test execution: November, 2025

Description of Metric

The following outlines the metrics that have been identified to best demonstrate conformance to certification criteria § 170.315(g)(10) Standardized API for patient and population services — all data request across two use cases (single patient and population services).

Provide a standardized FHIR based API that supports bulk data requests to provide patients, providers, and niche specialty applications to consume patient data enabling improved interoperability improved patient care and better overall population health.

Metric	Description	Justification
PHR Access	Patient can retrieve FHIR API data from PHR app for 100 percent of encounters.	We chose to concentrate on the aspects of this criterion that would empower clinicians with flexibility in choosing new and innovative healthcare technology. Historically, it has been difficult for builders of niche applications to access necessary patient demographic and clinical data for smooth, seamless use of their applications. Likewise, clinicians have often felt forced to stick with cumbersome, difficult-to-use EHR technology because of the cost and complexity of migrating their patient data.
PHR Data Accuracy	In 100 percent of encounters from Step #1, PHR data matches data from EHR. This will be confirmed by visual validation of the following FHIR resources: <ul style="list-style-type: none"> - Demographics - Problems - Medications - Allergies 	

Associated Certification Criteria

Associated Certification Criteria	Relied Upon Software (if applicable)
§170.315 (g)(10) Standardized API for patient and population services	ConnectEHR +BulkFHIR

Test Procedure

Step	Testing Procedure	Expected Outcomes	Key Milestone Dates
These Test Steps Cover Single Patient API Access			
1	Identify Trading Partner (TP) and coordinate with TP for providing patients timely access to their ePHI using production data as described in this RWT plan.	<ul style="list-style-type: none"> Partner with PHR or identify existing PHR that can receive patient clinical data as described in this RWT plan. We recommend MyLinks (https://www.mylinks.com/) Ensure that PHR has functionality to access the Dynamic FHIR API, as described here. Partner with EHR that is integrated with the Dynamic FHIR API and Patient Portal modules of ConnectEHR. 	October, 2025

2	Patient A has encounter with care provider who uses EHR described above.	Encounter is created and visually confirmed	
3	Provider captures USCDiv1 data elements in EHR	USCDiv1 data elements are validated in the system	
4	Provider manually generates Care/Referral Summary C-CDA post-visit or ensures that the EHR generates one automatically.	C-CDA is confirmed for the specified patient	
5	Patient A uses Dynamic Patient Portal login to view clinical information	<ul style="list-style-type: none"> • Patient Portal automatically sends email reminder that Patient A has a new clinical document available. • Email reminder has a URL/hyperlink to the patient portal. • If patient hasn't already activated their portal account, portal account can be activated via Welcome Email or by an Administrator user 	
6	Patient A uses portal login credentials to log into PHR app	Specific patient ID and token are returned for authentication and data requests	
7	PHR app displays full set of data for each data category	<ul style="list-style-type: none"> • Dynamic FHIR API has transformed C-CDA into FHIR resources. • PHR app consumes FHIR resources to populate EHR data 	
8	PHR app returns full set of data for a given category	PHR app will display and all data to be displayed for each data category	
9	PHR app returns data in a computable format using specified standards.	Data is confirmed to be in XML or JSON format	
10	PHR app returns full and accurate data for a specific date and specific date range	<ul style="list-style-type: none"> • Step 10 is optional, if PHR app has the capability to filter by date range • Filtering data by a specific date returns data accurately and as expected • Filtering data by a specific date range returns data accurately and as expected 	
11	Via visual inspection, the data is verified to include Assessment, Plan of Treatment and Health concerns are specified as narrative text	Visually validate Assessment, Plan of Treatment and Health Concerns narrative text	
These Test Steps Cover Care Coordination via Third-Party App			
1a	Identify Trading Partner (TP) and coordinate with TP for providing patients timely access to their ePHI using production data as described in this RWT plan.	<ul style="list-style-type: none"> • Partner with a provider-centric app for improved patient care (e.g. growth charts, clinical decision support, patient charting). • Ensure that app has functionality to access the Dynamic FHIR API, as described here. • Partner with EHR that is integrated with the 	

		Dynamic FHIR API module of ConnectEHR.	
2a	Provider logs into app and triggers FHIR API data retrieval	<ul style="list-style-type: none"> The app connects to the FHIR API server and pulls down the specific FHIR resources from the EHR 	
3a	Provider views and validates data in app	<ul style="list-style-type: none"> Data is rendered correctly: Provider compares patient data in app to patient data in EHR and notes any discrepancies. 	
These Test Steps Cover Bulk Data for Care Coordination			
1b	Identify Trading Partner (TP) and coordinate with TP for providing patients timely access to their ePHI using production data as described in this RWT plan.	<ul style="list-style-type: none"> Partner with a provider-centric app that requires periodic bulk data downloads. Ensure that app has functionality to access the Dynamic FHIR API, as described here. Partner with EHR that is integrated with the Dynamic FHIR API module of ConnectEHR. 	
2b	Provider logs into app and views patient data	<ul style="list-style-type: none"> The app connects to the FHIR API server and pulls down the specific FHIR resources from the EHR 	
3b	Provider validates data in app	<ul style="list-style-type: none"> Data is rendered correctly: Provider compares patient data in app to patient data in EHR and notes any discrepancies. 	
12	Calculate and compile metrics		November, 2025

SCHEDULE OF KEY MILESTONES

Real World testing starts the first quarter of 2025. Each phase is expected to take the numbers of days listed in the date/timeframe column to complete with a final report to be completed either the end of 2025 or in Q1 of 2026. Timeframes may overlap depending on the phase.

Phase	Date/Timeframe
Release of documentation for the Real-World Testing to be provided to authorized representatives and providers. This includes surveys, specific instructions on what to look for, how to record issues encountered, and Customer Agreements.	90 days
Collection of information as laid out by the plan for the period.	90 – 180 days
Planned System updates to allow for collection of data after an update.	60 - 90 days
Follow-up with providers and authorized representatives on a regular basis to understand any issues arising with the data collection.	Ongoing
End of Real-World Testing period/final collection of all data for analysis.	90 Days

Planned Date	Key Milestones*
January 1, 2025	<ul style="list-style-type: none"> • Begin collection data as laid out in the RWT Plan.
February 1, 2025	<ul style="list-style-type: none"> • Partner with PHR or identify existing PHR that can receive patient clinical data as described in this RWT plan. • Ensure that PHR has functionality to access the Dynamic FHIR API, as described here. • Partner with EHR that is integrated with the Dynamic FHIR API and Patient Portal modules of ConnectEHR • Partner with a provider-centric app that requires periodic bulk data downloads. • Ensure that app has functionality to access the Dynamic FHIR API, as described here. • Partner with EHR that is integrated with the Dynamic FHIR API module of ConnectEHR. • Import live patient data • Reconcile imported allergy, medication, and problem data with existing data
February 15, 2025	<ul style="list-style-type: none"> • Care provider selects recipient from directory of Direct addresses and initiates sending of Clinical Document. The user is able to create a C-CDA Release 2.1 that also includes the reason for referral, and the referring or transitioning provider's name and office contact information. • C-CDA Care Referral or Referral Note is triggered to send via Direct Protocol • Care provider reviews the Direct Status screen (under Direct Outgoing menu choice) to ensure Clinical Document was successfully transmitted. • Visually validate Assessment, Plan of Treatment and Health Concerns narrative text
March 15, 2025	<ul style="list-style-type: none"> • Recipient uses scorecard to grade C-CDA • Tester uses Document Center to locate Clinical Document. • Care provider reviews the Direct Status screen (under Direct Outgoing menu choice). • Recipient validates that Social History section of C-CDA is flagged as restricted • Encounter is created and visually confirmed • Dynamic FHIR API has transformed C-CDA into FHIR resources. • PHR app consumes FHIR resources to populate EHR data • Data is rendered correctly: Provider compares patient data in app to patient data in EHR and notes any discrepancies.
April 1, 2025	<ul style="list-style-type: none"> • Calculate and compile metrics for Quarter 1 • Begin collection for Quarter 2
July 1, 2025	<ul style="list-style-type: none"> • Calculate and compile metrics for Quarter 2 • Begin Collection for Quarter 3
October 1, 2025	<ul style="list-style-type: none"> • Calculate and compile metrics for Quarter 3 • Begin Collection for Quarter 4
October 15, 2025	<ul style="list-style-type: none"> • Confirm Trading Partner • Confirm ability to send and receive clinical documents • Confirm with TP that production data will be used, whether in an actual live environment or a copy of a live environment • Using production data in an actual live environment or copy of live environment, demonstrate the ability to export the full set of data for a single patient. • Using production data in an actual live environment or copy of live environment, demonstrate the ability to export the full set of data present in the EHR.
January 1, 2026	<ul style="list-style-type: none"> • Calculate and compile metrics for Quarter 4

February 1, 2026	<ul style="list-style-type: none"> Analysis, report creation, and submission of Real World Testing report to ACB (per their instructions).
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*Milestones highlighted in blue will be repeated in each quarter collected.

ATTESTATION

This Real World Testing plan is complete with all required elements, including metrics that address all certification criteria and care settings. All information in this plan is up to date and fully addresses the health IT developer’s Real World Testing requirements.

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Date	11/04/2024

ⁱ Certified health IT continues to be compliant with the certification criteria, including the required technical standards and vocabulary codes sets; certified health IT is exchanging EHI in the care and practice settings for which it is marketed for use; and EHI is received by and used in the certified health IT. (85 FR 25766)

ⁱⁱ <https://www.federalregister.gov/d/2020-07419/p-3582>